



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	50274/007002	5150
21559	7590	09/18/2009		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 09/18/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/04/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 42, 43, 45-49 and 59-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 42, 43, 45-49 and 59-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2009 has been entered.

2. Claims 1, 4, 42, 43, 45-49 and 59-67 are pending.

Claims 1, 43, 45-49, 59 and 60 have been amended.

Claims 57 and 58 have been cancelled.

Claims 61-67 have been added.

Claims 1, 4, 42, 43, 45-49 and 59-67 are examined on the merits.

New Grounds and Maintained Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1, 4, 42, 43, 45-49, 59, 60 and new claims 61-67 under 35 U.S.C. 102(b) as being anticipated by Vollmers et al. (Cancer 76(4): 550-558, August 15, 1995/IDS reference submitted January 26, 2004), as evidenced by Hensel et al. (Cancer Research 59: 5299-5306, October 15, 1999/IDS reference submitted January 4, 2002) is maintained and made. Claims 57 and 58 have been cancelled.

Applicants have amended claim 1 to recite a *purified* glycoprotein and consequently assert Vollmers does not anticipate the claims, see Remarks submitted May 4, 2009, pages 7 and 8. Applicants assert Vollmers does not inherently contain the *purified* glycoprotein while submitting Vollmer may contain the glycoprotein and this admission does not read on a *purified* glycoprotein, see page 8 of the Remarks. Applicants point to pages 28 and 29 of the specification and a Declaration of Dr. Frank Hensel, filed November 1, 2007 in support of the amendments, as well as the description of purification. These points of view and arguments have been carefully considered, but found unpersuasive.

Foremost, Applicants' specification and particularly pages 28 and 29 do not set forth a definition of the term "purified". Claims are examined in a manner in which they are given the broadest reasonable interpretation, hence purified is understood in the instant case to mean the claimed purified glycoprotein is free from its original state, i.e. cell itself. The definition of the term "purified" is not limited to Dr. Hensels' statement suggesting sequential size-exclusion and anion-exchange chromatography and the additional steps therein are required to purify the 82 kD protein. Terms within a claim are given the broadest reasonable construction consistent with the specification,

however absent a definition in the specification the breadth of the claim is expansive and wide-ranging. Claim language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. The teachings are remiss.

Vollmers discloses a tumor cell line 23132 (stomach carcinoma), which is the same as that initially noted in claim 1, line 5, see page 553, Figure 2 and column 2, *In vivo*...section. This cell line inherently has a glycoprotein comprising the human amino acid primary structure of CD55 and a tumor-specific N-linked glycostructure and exhibits and possesses the same properties as that claimed. This disclosed cell line comprises the said structure and glycostructure with a relative molecular mass of approximately 82kDa as evidenced by Hensel. The 23132 cell extract isolated in Vollmers is the same as Hensel's and inherently contains the same glycoprotein of about 82kDa, see Vollmers page 552, Western Blots sections and Hensel, page 5300, first column, Purification... section.

Applicants are reminded of *Atlas Powder Co. V. IRECO, Inc* 51 USPQ2d 1943 (Fed. Cir. 1999). Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient, which is inherently contained, in the prior art. Hence, the rejection is maintained.

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between 7:30 am to 6:30 pm, Monday through Saturday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
09 September 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643